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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,219	12/21/2001	Marc Vidal	10974-239005/MGH-0792.4 V	1413
26161	7590	10/22/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/027,219	VIDAL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 August 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 108 and 149-160 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 150-154 is/are allowed.
- 6) Claim(s) 108, 149 and 155-160 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II (originally claims 108-130 and 141) in the reply filed on August 9, 2004 is acknowledged. Claims 109-148 were subsequently cancelled in the election response, and new claims 149-160 were presented as pertaining to the elected subject matter. Claims 108 and 149-160 are pending and under consideration in the instant application.

### ***Information Disclosure Statement***

The information disclosure statement filed October 7, 2002 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action. It is noted that reference AV is a reference to a patent Application, which published as considered reference AC (US 5,695,941). Reference AV has been lined through because the Office does not print US Application numbers as references on a patent, although the reference has been considered as indicated by the initialing of the corresponding US Patent.

### ***Specification***

The disclosure is objected to because of the following informalities: the Brief Description of Figure 2 appears to be a duplication of the description of Figure 10A. Specifically, it is noted that Figure 2 does not include SEQ ID NOS: 7-10, as indicated in the description. A review of the sequence listing indicates that Figure 2 contains SEQ ID NOS: 5-6, instead. It would be

remedial for Applicant to provide a correct description of Figure 2, including reference to SEQ ID NOS: 5-6.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 155-160 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Claim 155 (and its dependent claims) comprises a limitation whereby a cell is provided that has “a third counterselectable reporter gene” (see for example section (iii) of claim 155). There is no support for this limitation in the specification as originally filed. At best, Applicant has support for a cell that comprise a “counterselectable” reporter gene, a “selectable” reporter gene, and a “screenable” gene (see for example page 42, lines 11-30). Since this does not provide for the opportunity of having three counterselectable genes in a given cell, the limitation of providing a cell that has “a third counterselectable reporter gene” is considered New Matter.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 108 and 149 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 83, 86, 92, 98 and 99 of U.S. Patent No. 5,955,280 (henceforth the '280 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 108 and 149 are obvious combinations of the limitations set forth in claims 83, 86, 92, 98 and 99 of the '280 patent.

Specifically, claim 86 of the '280 patent (based on its dependence of claim 83), recites a method of determining the interaction between two fusion genes by detecting the expression of a counterselectable reporter gene. Thus a desirable species of claim 83 makes use of a counterselectable marker. However, claim 86 does not specifically claim steps (c), (d) and (e) of instant claims 108 and 149, nor does the '280 patent contain a claim dependent on claim 86 that recites those steps.

Significantly, subsequent claims of the '280 patent which are also dependent on claim 83 address these limitations. In particular, claim 92 of the '280 patent contains the limitation for "isolating a cell which expresses each of said reporter genes" (corresponding to step (c) of the

instant claims), while claims 98 and 99 (both dependent on claim 92) contain the limitations for “amplifying at least a portion of a fusion gene of said isolated cell” (corresponding to step (d) of the instant claims) and “sequencing at least a portion of a fusion gene of said isolated cell” (corresponding to step (e) in claim 149), respectively. Thus, it is clearly desirable from these claims to further isolate a cell, amplify at least a portion of a fusion gene from said cell, and sequence at least a portion of that fusion gene when the expression of any reporter gene is detected; it is also clearly desirable (from claim 86) to use a counterselectable reporter gene to detect an interaction. Thus, it would be obvious to isolate a cell, amplify at least a portion of a fusion gene and sequence at least a portion of a fusion gene when using a counterselectable reporter gene because using a counterselectable reporter gene is a claimed species of the method from which claims 92, 98 and 99 depend (claim 83). One would have been motivated to combine the limitations of these claims in order to procure protection for a specifically claimed variation of the inventive method. As such, claims 83, 86, 92, 98 and 99 render claims 108 and 149 of the instant application obvious.

*Allowable Subject Matter*

Claims 150-154 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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AU 1636